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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/534,227

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Markus Loffler

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FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
LLP

901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER

DEAK, LESLIE R

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/534,227	Applicant(s) LOFFLER ET AL.	
	Examiner LESLIE R. DEAK	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 and 21-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 and 21-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/6/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-6, 16-19, 21-23, and 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,551,672 to Hessok in view of US 6,645,191 to Knerr et al.

In the specification and figures, Hessok discloses a container substantially as claimed by Applicant.

With regard to claims 1, 5, 6, 16-19 Hessok discloses a container having a wall structure with at least one polymer material wherein the polymer material comprises a cycloolefin polymer or a cycloolefin copolymer (see column 6, lines 18-34). The container is suitable for medical substances.

Hessok does not specifically disclose that the container comprises an acid. Knerr discloses a multi-chambered polymer container for dialysis solutions comprising at least two chambers 2, 3, separated by seal 4, wherein compartment 3 comprises concentrated hydrochloric acid and compartment 2 comprises glucose solution, a carbohydrate (see column 4, lines 40-53). Therefore, it would have been obvious to provide the container disclosed by Hessok with an acid solution as disclosed by Knerr, since Hessok discloses that the container is suitable for medical solutions, and the solutions in the container disclosed by Knerr are for a medical purpose.

With regard to claims 2-4 and applicant's limitations drawn to the performance of the cycloolefin polymer during specific tests, it is the position of the Examiner that since Hessok discloses the same material, the polymer disclosed by Hessok necessarily generates the same results from the claimed tests. That is, since Hessok discloses the claimed material, the burden rests with the Applicant to prove that the material disclosed by Hessok is materially different, and performs differently under the claimed tests, in order to distinguish the instantly claimed material from that disclosed by Hessok.

With regard to claims 21 and 26, the cited prior art suggests the method of providing the claimed container and storing a medical solution therein.

With regard to claim 22, the cited prior art suggests the claimed system, since the system comprises only the claimed container.

With regard to claim 23, Knerr discloses that the apparatus may comprise a third compartment (see column 4, lines 10-31) that may comprise a water reservoir. Knerr discloses that the compartments may comprise a glucose concentrate and an acid component that comprises electrolytes (see columns 3-4). Therefore, it would have been obvious to provide the container disclosed by Hessok with an acid solution as disclosed by Knerr, since Hessok discloses that the container is suitable for medical solutions, and the solutions in the container disclosed by Knerr are for a medical purpose.

With regard to claim 25, Knerr discloses that the claimed container is used to provide dialysis treatment, suggesting the treatment method claimed by applicant.

3. Claims 8-10 and 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,551,672 to Hessok in view of US 6,645,191 to Knerr et al, further in view of US 6,713,165 to Karsten.

In the specification and figures, Hessok and Knerr suggest the apparatus substantially as claimed by applicant.

With regard to claims 8 and 9, the cited prior art fails to specifically define the polymer material. Karsten discloses a multilayer polymer structure that may be used for medical containers (see column 9, lines 1-10), wherein one of the layers may comprise a cycloolefin copolymer that is amorphous and based on cycloolefins (see column 3, line 45 to column 4, line 17). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the materials disclosed by Karsten in the medical fluid container suggested by the prior art since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. See MPEP § 2144.07.

With regard to claims 10, 12, and 13, Karsten discloses that the structure may comprise several layers, one of which may comprise EVOH (see column 5, lines 55-60). Since Applicant discloses that EVOH has a high water uptake, it is the position of the Examiner that the EVOH disclosed by Karsten necessarily has a high water uptake as claimed by applicant. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the materials disclosed by Karsten in the medical fluid container suggested by the prior art since it has been held to be within the

general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. See MPEP § 2144.07.

With regard to claim 11, Karsten discloses that the layers of the multilayer polymer structure, one of which includes cycloolefins, may be disposed in various configurations depending on the application of the container (see column 9, generally). Hessok discloses that the container comprises cycloolefins that contact the contents of the container (see, generally, column 6). As such, the cited prior art reasonably suggests to one having ordinary skill in the art that the polymer layer comprising cycloolefins may face the interior of the container if needed.

With regard to claims 14 and 15, Karsten discloses that the film may be made of multiple layers of coextruded film (see column 8, lines 5-6) that may comprise polyethylene, cycloolefins, and polyamides (see column 5, lines 42-65), arranged as needed for the desired application. Accordingly, the cited prior art reasonably suggests the configuration claimed by applicant.

4. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,551,672 to Hessok in view of US 6,645,191 to Knerr et al, further in view of US 5,211,643 to Reinhardt et al.

In the specification and figures, Hessok and Knerr suggest the apparatus substantially as claimed by applicant.

With regard to claim 24, the cited prior art fails to specifically recite that the concentrates within the container comprise pH values that, after mixing, result in a

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solution in the claimed pH range. Reinhardt discloses a multi-chambered dialysis solution container wherein the concentrates are selected to provide a mixed solution with a pH of about 7.6 in order to provide a dialysis solution with a physiological pH value (see, generally, column 4). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to select concentrates with appropriate pH values as disclosed by Reinhardt to place in the container suggested by the cited prior art in order to provide a dialysis solution with a physiological pH, as taught by Reinhardt.

5. As an alternative to the rejection above, claims 1-6, 16-19, 21-23, and 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over DE 19916141 to Jacobs in view of US 6,645,191 to Knerr et al.

With regard to claims 1, 5, 6, 16-19 Jacobs discloses a container having a wall structure with at least one polymer material wherein the polymer material comprises a cycloolefin polymer or a cycloolefin copolymer (see English language abstract). The container is suitable for medical substances.

Jacos does not specifically disclose that the container comprises an acid. Knerr discloses a multi-chambered polymer container for dialysis solutions comprising at least two chambers 2, 3, separated by seal 4, wherein compartment 3 comprises concentrated hydrochloric acid and compartment 2 comprises glucose solution, a carbohydrate (see column 4, lines 40-53). Therefore, it would have been obvious to provide the container disclosed by Jacobs with an acid solution as disclosed by Knerr,

since Jacobs discloses that the container is suitable for medical solutions, and the solutions in the container disclosed by Knerr are for a medical purpose.

With regard to claims 2-4 and applicant's limitations drawn to the performance of the cycloolefin polymer during specific tests, it is the position of the Examiner that since Jacobs discloses the same material, the polymer disclosed by Jacobs necessarily generates the same results from the claimed tests. That is, since Jacobs discloses the claimed material, the burden rests with the Applicant to prove that the material disclosed by Jacobs is materially different, and performs differently under the claimed tests, in order to distinguish the instantly claimed material from that disclosed by Jacobs.

With regard to claims 21 and 26, the cited prior art suggests the method of providing the claimed container and storing a medical solution therein.

With regard to claim 22, the cited prior art suggests the claimed system, since the system comprises only the claimed container.

With regard to claim 23, Knerr discloses that the apparatus may comprise a third compartment (see column 4, lines 10-31) that may comprise a water reservoir. Knerr discloses that the compartments may comprise a glucose concentrate and an acid component that comprises electrolytes (see columns 3-4). Therefore, it would have been obvious to provide the container disclosed by Hessok with an acid solution as disclosed by Knerr, since Jacobs discloses that the container is suitable for medical solutions, and the solutions in the container disclosed by Knerr are for a medical purpose.

With regard to claim 25, Knerr discloses that the claimed container is used to provide dialysis treatment, suggesting the treatment method claimed by applicant.

6. Claims 8-10 and 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over DE 19916141 to Jacobs in view of US 6,645,191 to Knerr et al, further in view of US 6,713,165 to Karsten.

In the specification and figures, Jacobs and Knerr suggest the apparatus substantially as claimed by applicant.

With regard to claims 8 and 9, the cited prior art fails to specifically define the polymer material. Karsten discloses a multilayer polymer structure that may be used for medical containers (see column 9, lines 1-10), wherein one of the layers may comprise a cycloolefin copolymer that is amorphous and based on cycloolefins (see column 3, line 45 to column 4, line 17). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the materials disclosed by Karsten in the medical fluid container suggested by the prior art since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. See MPEP § 2144.07.

With regard to claims 10, 12, and 13, Karsten discloses that the structure may comprise several layers, one of which may comprise EVOH (see column 5, lines 55-60). Since Applicant discloses that EVOH has a high water uptake, it is the position of the Examiner that the EVOH disclosed by Karsten necessarily has a high water uptake as

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claimed by applicant. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the materials disclosed by Karsten in the medical fluid container suggested by the prior art since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. See MPEP § 2144.07.

With regard to claim 11, Karsten discloses that the layers of the multilayer polymer structure, one of which includes cycloolefins, may be disposed in various configurations depending on the application of the container (see column 9, generally). As such, the cited prior art reasonably suggests to one having ordinary skill in the art that the polymer layer comprising cycloolefins may face the interior of the container if needed.

With regard to claims 14 and 15, Karsten discloses that the film may be made of multiple layers of coextruded film (see column 8, lines 5-6) that may comprise polyethylene, cycloolefins, and polyamides (see column 5, lines 42-65), arranged as needed for the desired application. Accordingly, the cited prior art reasonably suggests the configuration claimed by applicant.

7. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over DE 19916141 to Jacobs in view of US 6,645,191 to Knerr et al, further in view of US 5,211,643 to Reinhardt et al.

In the specification and figures, Jacobs and Knerr suggest the apparatus substantially as claimed by applicant.

With regard to claim 24, the cited prior art fails to specifically recite that the concentrates within the container comprise pH values that, after mixing, result in a solution in the claimed pH range. Reinhardt discloses a multi-chambered dialysis solution container wherein the concentrates are selected to provide a mixed solution with a pH of about 7.6 in order to provide a dialysis solution with a physiological pH value (see, generally, column 4). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to select concentrates with appropriate pH values as disclosed by Reinhardt to place in the container suggested by the cited prior art in order to provide a dialysis solution with a physiological pH, as taught by Reinhardt.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LESLIE R. DEAK whose telephone number is (571)272-4943. The examiner can normally be reached on Monday - Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie R. Deak/
Primary Examiner
Art Unit 3761
18 April 2008